AUG 0 6 2002

K021974

Section C. 510(k) Summary

In accordance with the requirements of SMDA 1990, and 21 CFR 807.92, this 510(k) Summary is provided:

Submitter: Medtronic MiniMed 18000 Devonshire Street Northridge, CA 91325

Contact: Gerda Resch, Regulatory Affairs; (818) 576-4198; gerda.resch@minimed.com

Name Of Device: Medtronic MiniMed ComLink, model 7304, and Medtronic MiniMed Solutions™ software, model 7311

Predicate Device: Com-Station™ Communication System

Description Of The Device: The Medtronic MiniMed ComLink Communication System is a data transfer system consisting of a hardware component designated by Medtronic MiniMed model number 7304 and a software component designated by model number 7311.

The system is designed for use with Medtronic MiniMed infusion pump (model 511). The hardware component of the ComLink consists of a radio-frequency (RF) transceiver enclosed in a plastic housing and one female RS-232 compatible serial communications port. Data is downloaded via RF telemetry to transfer data from the pump to a personal computer. The ComLink converts RF signals into RS-232 compatible electrical pulses, which are sent through a serial port to the PC.

Intended Use Of The Device: The Medtronic MiniMed ComLink (model 7304) and model 7311 software are intended for use by patients at home and clinicians in a medical office setting to communicate with devices that utilize Paradigm pump compatible RF telemetry (i.e. MMT-511). MMT-7304 is intended for use in downloading device information when commanded by MMT-7311 operating on a PC and MMT-7304 is connected in line with the PC's serial port.

Comparison Of The Technological Features Of The New Device And Predicate Device: The technological features of the new device do not differ significantly from the predicate device. The minor differences are that the Com-Station™ Communication System transfers data via Infa-Red (IR) while the ComLink Communication System utilizes RF signals, the Com-Station derives its power from an electrical outlet whereas the ComLink is indirectly powered by PC, the ComLink does not have a cradle, and finally can only download pump information from pumps with RF telemetry.

Gerda Resch, RAC — Date
Manager, Regulatory Affairs
Medtronic MiniMed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 6 2002

Ms. Gerda Resch
Manager, Regulatory Affairs
Medtronic MiniMed
18000 Devonshire Street
Northridge, California 91325

Re: K021974
Trade/Device Name: Medtronic MiniMed ComLink™ Communication System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ
Dated: June 15, 2002
Received: June 17, 2002

Dear Ms. Resch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K021974

Device Name: Medtronic MiniMed ComLink Model 7304 and software Model 7311

Indications For Use: For use by patients at home and clinicians in a medical office setting to communicate with devices that utilize Paradigm pump compatible RF telemetry (i.e. MMT-511). MMT-7304 is intended for use in downloading device information when commanded by MMT-7311 operating on a PC and MMT-7304 is connected in line with the PC's serial port.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ **or** **Over-the-Counter Use** __X__
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, D ntal Devices

510(k) Number: K021974